

**RECEIVED  
CENTRAL FAX CENTER****MAY 28 2009**Docket No.: 56792(71699)  
(PATENT)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Daniel W. Chan et al.

Application No.: 10/500,838

Confirmation No.: 1171

Filed: February 2, 2005

Art Unit: 1643

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For: **BIOMARKERS FOR DETECTING OVARIAN  
CANCER**

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Examiner: A. M. Harris

Mail Stop Petitions  
Commissioner for Patents  
P.O. Box 1450,  
Alexandria, VA 22313-1450**PETITION TO WITHDRAW THE HOLDING OF ABANDONMENT  
UNDER 37 C.F.R. 1.181**

Sir:

This is a Petition under Rule 1.181 for withdrawal of the holding of abandonment in the above-captioned matter on the grounds that the Examiner improperly mailed a Notice of Abandonment prior to the end of the statutory period.

**STATEMENT OF FACTS**

1. A Notice of Abandonment was received by Applicants on April 30, 2009. The Notice stated that the application was abandoned for failure to timely file a proper reply to the office action mailed on December 4, 2008. A copy of the Notice of Abandonment is attached hereto as Appendix A.

2. Applicants filed a Response to the Office Action dated on April 30, 2008 by facsimile on October 29, 2008, along with a Three Month Extension of Time. A copy of the

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Response and the Extension of Time as obtained from PAIR are attached hereto as Appendix B and Appendix C, respectively.

3. Also on October 29, 2008, Applicants filed a Notice of Appeal. A copy of the Notice of Appeal as obtained from PAIR is attached hereto as Appendix D.

### **RELIEF REQUESTED**

Applicants respectfully request, based on the foregoing facts and statements and the following arguments, that the Commissioner withdraw the holding of abandonment and reinstate the subject application to pending status.

### **ARGUMENT**

The Notice of Appeal was filed on October 29, 2008. Applicants have two months from this date (i.e., December 29, 2008) to file an Appeal Brief or a Request for Continued Examination. Moreover, Applicants have an additional five months from December 29, 2009 (i.e., May 29, 2009) available with the payment of extension fees.

Therefore, the Notice of Abandonment was improperly issued on April 30, 2009, which was prior to the May 29, 2009 deadline.

This Petition and the related enclosures are being filed within two (2) months of the mailing date of the Notice of Abandonment. Accordingly, this petition is believed to be timely filed pursuant to 37 C.F.R. 1.181(f).

In the present case, Applicant has included the required statements by the practitioner, and provided appropriate supporting evidence. Accordingly, the present application should not have been considered to be abandoned, and Applicant requests that the application be restored to pending status.

**REQUIRED FEE**

There is no fee required for the submission of a Petition under Rule 181, and it is believed that no fee is due. However, if for any reason a fee is required for consideration of this Petition, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. 04-1105 under Order No. 56792(71699).

Dated: May 28, 2009

Respectfully submitted,

By 

Jonathan M. Sparks, Ph.D.

Registration No.: 53,624

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Attorneys/Agents For Applicant



## UNITED STATES PATENT AND TRADEMARK OFFICE

Appendix A

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,838	02/02/2005	Daniel W. Chan	56792(71699)	1171

49383 7590 04/30/2009  
EDWARDS ANGELL PALMER & DODGE LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER  
HARRIS, ALANA M

ART UNIT PAPER NUMBER  
1643

MAIL DATE DELIVERY MODE  
04/30/2009 PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

MAY 28 2009

<b>Notice of Abandonment</b>	Application No.	Applicant(s)	
	10/500,838	CHAN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**

This application is abandoned in view of:

- ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 04 December 2008.
  - ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - ☒ No reply has been received.
- ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - ☐ The issue fee and publication fee, if applicable, has not been received.
- ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - ☐ No corrected drawings have been received.
- ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
- ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
- ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
- ☐ The reason(s) below:

/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

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EAP&D 617 227 4420

NO. 9494 P. 8

Appendix B

OCT. 29. 2008 11:34AM

EAP&D 617 227 4420

RECEIVED  
CENTRAL FAX CENTER NO. 7563 P. 7  
OCT 29 2008

Docket No.: 56792(71699)  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Daniel W. Chan et al.

Application No.: 10/500,838

Confirmation No.: 1171

Filed: February 2, 2005

Art Unit: 1643

For: BIOMARKERS FOR DETECTING OVARIAN  
CANCER

Examiner: A. M. Harris

**AMENDMENT IN RESPONSE TO FINAL OFFICE ACTION**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTORY COMMENTS**

In response to the Office Action dated April 30, 2008, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** begin on page 2 of this paper.

**Remarks/Arguments** begin on page 8 of this paper.

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PAGE 7/14 \* RCVD AT 10/29/2008 12:30:30 PM [Eastern Daylight Time] \* SVR:USPTO-EFAX-5/12 \* DNS:2738300 \* CSID: \* DURATION (mm:ss):02:22

PAGE 8/27 \* RCVD AT 5/28/2009 12:55:03 PM [Eastern Daylight Time] \* SVR:USPTO-EFAX-5/35 \* DNS:2738300 \* CSID: \* DURATION (mm:ss):03:18

Application No. 10/600,838

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Docket No.: 56792(71639)

AMENDMENTS TO THE CLAIMS

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CENTRAL FAX CENTER  
OCT 29 2008

Claims 1-2. (cancelled)

Claim 3. (Previously Presented) A method for detection and diagnosis of ovarian cancer comprising:

measuring at least one protein biomarker in a subject sample, wherein the protein markers are selected from:

- Marker I: having a molecular weight of about 8.6 kD
- Marker II: having a molecular weight of about 9.2 kD
- Marker III: having a molecular weight of about 19.8 kD
- Marker IV: having a molecular weight of about 39.8 kD
- Marker V: having a molecular weight of about 64 kD
- Marker VII: having a molecular weight of about 79 kD

and;

correlating the measurement of one or more protein biomarkers with a diagnosis of ovarian cancer, wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer.

Claim 4. (original) The method of claim 3 wherein one or more protein biomarkers are used to diagnose ovarian cancer.

Claim 5. (Previously Presented) The method of claim 3 wherein a plurality of the biomarkers are detected.

Claims 6-8. (cancelled)

Claim 9. (Currently Amended) The method of claim 3 wherein a single biomarker is used in combination with one or more additional known cancer biomarkers for diagnosing cancer.

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Docket No.: 56762(71689)

Claim 10. (Currently Amended) The method of claim 3 wherein a plurality of the markers are used in combination with one or more additional known cancer markers for diagnosing cancer.

Claim 11. (Currently Amended) The method of claim 9 or 10 wherein the additional known cancer markers are ovarian cancer markers for diagnosing ovarian cancer.

Claim 12. (Currently Amended) The method of 11 wherein the additional known ovarian cancer marker is CA 125.

Claims 13-33. (cancelled)

Claim 34. (Previously Presented) The method of claim 3 wherein one or more of the markers are detected using laser desorption/ionization mass spectrometry, comprising:

providing a probe adapted for use with a mass spectrometer comprising an adsorbent attached thereto;  
contacting the subject sample with the adsorbent, and;  
desorbing and ionizing the marker or markers from the probe and detecting the desorbed/ionized markers with the mass spectrometer.

Claims 35-38. (cancelled)

Claim 39. (Previously Presented) The method of claim 3 wherein at least one or more protein biomarkers are detected using immunoassays.

Claim 40. (original) A process for purification of a biomarker, comprising fractionating a sample comprising one or more protein biomarkers by size-exclusion chromatography and collecting a fraction that includes the one or more biomarker; and/or fractionating a sample comprising the one or more biomarkers by anion

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NO. 9494 P. 11

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exchange chromatography and collecting a fraction that includes the one or more biomarkers.

Claims 41-61. (cancelled)

Claim 62, (Previously Presented) The method of claim 3 wherein the stage of ovarian cancer is assessed.

Claims 63-84. (cancelled)

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PAGE 10/14 \* RCVD AT 10/29/2008 12:33:30 PM [Eastern Daylight Time] \* SVR:USPTO-EFXRF-5/12 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):02:22

PAGE 11/27 \* RCVD AT 5/28/2009 12:55:03 PM [Eastern Daylight Time] \* SVR:USPTO-EFXRF-5/35 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):03:18

Application No. 10/500,838

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Docket No.: 58782(71699)

**REMARKS**

Claims 3-5, 9-12, 34, 39 and 62 are pending in the application. Claims 10-12 have been amended by the amendments presented herein. Accordingly, once the amendments presented herein have been entered, claims 3-5, 9-12, 34, 39 and 62 will remain pending. No new matter has been added.

***Rejection of Claims 3-5, 9, 10-12, 34, 39, and 62 Under 35 U.S.C. 112***

The Examiner has rejected claims 3-5, 9-12, 34, 39 and 62 under 35 USC 112, first paragraph failing to comply with the written description requirement. The examiner believes that the specification does not teach "wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer." Applicants disagree. Applicants point the Examiner's attention to Example 1, page 47 of the application. The results of Example 1 clearly indicate that "at 9.2kD, 19.8kD, and 60kD showed higher expression levels on average among the specimens from the cancer patients compared to the controls while the remaining peaks demonstrated the inverse expression pattern." The marker of 9.2kD is Marker II and the marker of 19.8kD is Marker III. Accordingly, the application as filed provides support for the amendment presented in the last response to office action.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

***Rejection of Claims 9-12 Under 35 USC 112***

The Examiner has rejected claims 9-12 as being indefinite in the recitation of the term "known biomarker". Based on the teachings in the specification, Applicants believe the term "known biomarker" is clear and definite. However, in the interest of expediting prosecution, and in no way acquiescing to the validity of the Examiner's rejection, Applicants have amended the claim to recite "additional biomarker".

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Applicants believe that this amendment will overcome the Examiner's rejection, and therefore, respectfully request withdrawal of this rejection.

***Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 102(e)***

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being anticipated by US Patent Application Publication No.: 2003/0003479. Specifically, the Examiner indicates that the '479 publication discloses methods for detecting, characterizing and staging ovarian cancers comprising correlating changes in levels of expression of marker genes with the presence of ovarian cancer. Applicants respectfully traverse this rejection.

As previously indicated, the markers disclosed in the '479 application are nucleic acid markers and not polypeptide markers. The Examiner is of the opinion that that '479 publication is enabling for detecting, characterizing and staging ovarian cancer by detecting the presence of one or more polypeptides corresponding to the nucleic acid molecules identified in the '479 application. However, this is not the case. The '479 publication provides no evidence of altered expression levels of the polypeptides corresponding to the identified nucleic acid molecules in disease state, i.e., in cancerous tissue.

Moreover, the Examiner indicates that markers O504, O512, and O517 correspond to Applicant's markers V, IV, and VII, respectively. Claim 1, as pending, is directed to a method of detecting and diagnosing ovarian cancer by measuring at least one of the identified protein biomarkers in a subject sample, and correlating the measurement of one or more protein biomarkers with a diagnosis of ovarian cancer, wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer. The '479 publication teaches that the biomarkers set forth in Table I (including O504, O512, and O517) are up-regulated in cancerous samples. The '479 publication states that "[m]arker genes for which significant increases in the levels of expression in cancer-related samples relative to non-cancerous samples were observed and listed in Table 1" (see paragraph [0343]).

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Accordingly, the '479 publication does not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

***Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 103(a)***

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being unpatentable over US Patent Application Publication No.: 2003/0003479 in view of US Patent Application Publication No.: 2003/0147106 and US Patent 5,650,291.

As indicated above, the '479 publication does not teach or suggest the claimed invention. Moreover, the '106 publication and the '291 patent do not make up for the deficiencies of the '479 publication. Accordingly, the combination of these documents would not put one of skill in the art in possession of the instant invention.

Therefore, Applicants respectfully request the reconsideration and withdrawal of the foregoing rejection.

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PAGE 13/14 \* RCVD AT 10/29/2008 12:33:30 PM [Eastern Daylight Time] \* SVR:USPTO-EFAXF-5/12 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):02-22

PAGE 14/27 \* RCVD AT 5/28/2009 12:55:03 PM [Eastern Daylight Time] \* SVR:USPTO-EFAXF-5/35 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):03-18

MAY. 28. 2009 12:53PM

EAP&D 617 227 4420

NO. 9494 P. 15

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EAP&D 617 227.4420

NO. 7563 P. 14

Application No. 10/800,838

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CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: October 30, 2008

Customer Number 21874

Respectfully submitted,

By

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Registration No.: 53,624

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PAGE 14/14 \* RCVD AT 10/29/2008 12:33:30 PM [Eastern Daylight Time] \* SVR:USPTO-EFAXF-5/12 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):02:22

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## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,838	02/02/2005	Daniel W. Chan	56792(71699)	1171
21874 7590 04/30/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 04/30/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

MAY 28 2009

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	10/500,838		CHAN ET AL.	
	Examiner		Art Unit	
	Alana M. Harris, Ph.D.		1643	

~ The MAILING DATE of this communication appears on the cover sheet with the correspondence address ~  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-5, 9-12, 34, 39, 40 and 62 is/are pending in the application.  
 4a) Of the above claim(s) 40 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 3-5, 9-12, 34, 39 and 62 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date, \_\_\_\_\_  
 5) ☐ Notice of Informal Patent Application  
 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Response to Amendments and Arguments***

1. Claims 3-5, 9-12, 34, 39, 40 and 62 are pending.  
Claim 40, drawn to non-elected inventions are withdrawn from examination.  
Claims 3 and 34 have been amended.  
Claims 35-38, 46, 47, 63, 65, 70 and 81-84 have been cancelled.  
Claims 3-5, 9-12, 34, 39 and 62 are examined on the merits.

### ***Withdrawn Objection***

#### ***Claim Objections***

2. The objection of claim 3 because of the following informality: it cites "...at least one protein biomarkers...", which was not grammatically correct has been withdrawn in light of Applicants submission of an amendment to the claim on February 11, 2008.

### ***Withdrawn Rejection***

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 3-5, 34, 39 and 62 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter set forth on page 3, section 5(a) of the first action on the merits (FAOM) which applicant regards as the invention is withdrawn in light of Applicants' amendment to claim 3 setting forth correlation steps.



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***Claim Rejections - 35 USC § 102***

4. The rejection of claims 3-5, 9-12, 39 and 62 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) is withdrawn in light of Applicants' amendments to claim 3.
5. The rejection of claims 3-5, 9-12, 39 and 62 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) is withdrawn in light of Applicants' amendments to claim 3.

***New and Maintained Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3-5, 9-12, 34, 39 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

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Page 4

Applicants have amended claim 3 to recite "wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer." However, Applicants have not pointed out support for this recitation. The Examiner has reviewed the specification and does not note where support for this amendment is found. At best the Examiner notes on page 17, lines 19-24 of the specification there is the broad contemplation of "a marker can be a polypeptide ...present at an elevated level or at a decreased level in samples...". There is no mention of specific markers that correspond to an increase or decrease in levels as set forth in claim 3. Applicants should list the page and line numbers within the disclosure that are commensurate with the new amendment or delete the new matter.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 9-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

a. Claims 9, 10 and 11 continue to be indefinite in the recitation "known biomarker". It is not clear if the markers set forth as Marker I-Marker V and Marker VII have already been established as ovarian cancer markers and what the recitation means. Applicants' arguments are concise and limited. They note they have amended

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claims for clarity, see page 5 of the Remarks submitted February 11, 2008. However, the cited claims have not been amended and the metes and bounds still cannot be determined. For the reasons of record the rejection is maintained.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. The rejection of claims 3-5, 9-11, 39 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent Application Publication number 2003/0003479 A1 (effective filing date April 19, 2001) is maintained.

Applicants argue the publication does not anticipate the claimed method because the markers disclosed in the publication are nucleic acid markers and not polypeptide markers and secondly, the publication does not teach or suggest the identification and/or [quantitation] of protein biomarkers, see page 6 of Remarks, 2nd paragraph. Moreover, Applicants assert "even if... the... publication did teach [the] biomarkers..., none of the nucleic acid markers disclosed correspond to the protein biomarkers set

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forth in the pending claims.", see Remarks, see Remarks, page 6, paragraph 4. These points of view and arguments have been carefully considered, but found unpersuasive.

The patent application publication discloses methods of detecting, characterizing and staging ovarian cancers comprising correlating changes in the levels of expression of marker genes with the presence of ovarian cancer, see abstract. The level of expression of the marker gene in a sample reads on detecting a protein encoded by a marker gene, or a polypeptide, see page 3, sections 0018 and 0019; claims 1-8 and 17-25. It is art known kD or kilodalton references proteins and not nucleic acids, hence the kDs cited beside the ovarian markers read on the atomic mass of the protein biomarkers.

Markers O49 (34 kD) and O82 (55 kD) are biomarkers that have molecular weights synonymous with Applicants' markers, Marker IV (of about 39.8 kD) and Marker V (of about 54 kD), respectively, see page 36.

Marker O316 (58kD) is a biomarker that has a molecular weight of about 54 kD and 60 kD, which corresponds to Marker V and CA 125, respectively, see page 39.

Markers O426 (52 kD) and O452 (36kD) are protein biomarkers having a molecular weight of about Marker V (54 kD) and Marker IV (39.8 kD), respectively, see page 40.

The publication's markers O504 (58 kD), O512 (40 kD) and O517 (72 kD) are within the range of Applicants' Markers V, IV and VII, respectively, see page 41.

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A variety of formats can be employed to determine whether a sample contains a biomarker, see page 29 - page 32.

Applicants further arguments remarking the disclosed protein have masses that are from 0.5% to 14.5% and different the protein biomarkers cited in the claims, see page 7, 6<sup>th</sup> paragraph. Applicants' claims read on molecular weights of about or within a range. All of the disclosed markers read on the protein biomarkers Applicants have cited. The rejection is maintained for the reasons established herein and of record.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The rejection of claims 3-5, 9-12, 34, 39 and 62 under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent Application Publication number 2003/0003479 A1 (effective filing date April 19, 2001), and further in view of U. S. Patent Application Publication number 2003/0137106 A1 (effective filing date March 9, 2001) and U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) is maintained.

Applicants argue the '479 publication does not teach or suggest the use of protein biomarkers for the detection of ovarian cancer and the proteins of the publication are not the same molecular weights as the biomarkers in the instant claims, see page 8,

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paragraph 2 of the Remarks. Applicants complete arguments asserting the secondary references do not make up for the deficiencies of the '479 publication, see 3<sup>rd</sup> paragraph. For the reasons presented in the 102(e) rejection the instant rejection is maintained.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
23 April 2008  
/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643

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Appendix C

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PTO/SB/22 (10-08)

**PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)**  
FY 2008  
(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4010).)

Application Number 10/600,838-Conf. #1171 Docket Number (Optional) 58792(71000)

Filed February 2, 2005

For **BIOMARKERS FOR DETECTING OVARIAN CANCER.**

Art Unit 1643 Examiner A. M. Harris

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$130	\$65	\$
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$490	\$245	\$
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1110	\$555	\$ <u>555.00</u>
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1730	\$865	\$
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2350	\$1175	\$

☒ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 04-1105

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 59,824

☐ attorney or agent under 37 CFR 1.34.  
Registration number missing under 37 CFR 1.34

Signature [Signature] Date October 29, 2008

Jonathan M. Sparks, Ph.D. (617) 517-5543  
Typed or printed name Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of 1 forms are submitted.

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PAGE 5/14 \* RCVD AT 10/29/2008 12:33:30 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXF-5/12 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):02:22

PAGE 26/27 \* RCVD AT 5/28/2009 12:55:03 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXF-5/35 \* DNIS:2738300 \* CSID: \* DURATION (mm:ss):03:18



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Appendix D

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**NOTICE OF APPEAL FROM THE EXAMINER TO  
 THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Docket Number (Optional)  
 56792(71699)

In re Application of  
 Daniel W. Chan et al.

Application Number  
 10/300,838-Conf. #1171 Filed February 2, 2005  
 For BIOMARKERS FOR DETECTING OVARIAN CANCER

Art Unit  
 1843 Examiner  
 A. M. Harris

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) \$ 640.00

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: \$ 270.00

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 04-1105.

☒ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: INFORMATION ON THIS FORM MAY BECOME PUBLIC. CREDIT CARD INFORMATION SHOULD NOT BE INCLUDED ON THIS FORM. PROVIDE CREDIT CARD INFORMATION AND AUTHORIZATION ON PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.  
 See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ attorney or agent of record.  
 Registration number 53,624

☐ attorney or agent acting under 37 CFR 1.34.  
 Registration number if acting under 37 CFR 1.34. \_\_\_\_\_

Signature  
 Jonathan M. Sparks, Ph.D.  
 Typed or printed name

(617) 617-5543  
 Telephone number

October 29, 2008  
 Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of 1 forms are submitted.

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PAGE 27/27 \* RCVD AT 5/28/2009 12:55:03 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXRF-5/35 \* DNIS:2738300 \* CSID: \* DURATION (mm-ss):03-18